

**REMARKS**

Upon entry of the present amendment, claims 1-9 and 56-60 will be pending and stand rejected.

***Rejections Under 35 U.S.C. § 103(a)***

Claims 1-2, 9, and 56-60 stand rejected for alleged obviousness over the Reiley patent in view of U.S. Pub. No. 2001/0025157 to Kriesell (“the Kriesell publication”).

**Matters Previously Addressed by Applicants**

Applicants previously demonstrated that the posited combination is not one that a skilled artisan would have been motivated to make, and that even if there existed sufficient motivation (a point not conceded by the Applicants), the resulting combination would not result in any claimed invention. First, Applicants demonstrated that the sole rationale presented by the Office as to why it would have allegedly been obvious to one skilled in the art to modify the tip of the catheter of the Reiley patent by providing a “porous delivery tip” as disclosed by the Kriesell publication (*i.e.*, in order to provide a tip that “permit[s] the medicinal fluid to flow uniformly outward of the tip” – *see* 4/9/08 Office Action at paragraph bridging pages 2 and 3) is undermined by the teachings of the primary reference. *See* 7/9/08 Reply at paragraph bridging pages 4 and 5. Second, Applicants showed that the posited combination would have been thought by one skilled in the art to render the tool system of the Reiley patent unsatisfactory for its intended purpose, at least because one of ordinary skill in the art would not believe that a tip that is adapted for delivery of a small volume at an ultra low controlled flow rate over very long periods of time, such as the tip taught by the Kriesell patent, would be suitable for use with the system disclosed by the Reiley patent, concerning which the ability to deliver comparatively large volumes in as brief a period of time as possible are vital characteristics (*see* 7/9/08 Reply at pages 5-6). Additionally, Applicants demonstrated that there is no evidence that the Kriesell publication teaches or suggests a tip having about 60% to about 90% porosity (as recited in pending claim 1), and accordingly that even if the skilled artisan were motivated to combine the Reiley patent and the Kriesell publication in the manner suggested by the Office, the posited combination would not result in any claimed invention (*see* 7/9/08 Reply at paragraph bridging pages 6 and 7).

New Issues

The Office has presently responded to Applicants' demonstration of the fact that the posited combination would render the tool system of the Reiley patent unsatisfactory for its intended purpose by alleging that "the combination is perfectly satisfactory, since the intended use of both references is to deliver a material" (10/14/08 Office Action at page 4). However, the Office's response disregards the showing made by Applicants that although the Reiley patent and the Kriesell patent bear relevance to one another in the limited sense that they both generally involve delivery of a material<sup>1</sup>, the mechanical adaptations that are viewed as essential to such delivery differ greatly between the respective references. For example, the tool system of the Reiley patent requires the ability to dispense comparatively *large volumes* of bone restorative material (for example, adequate quantities of material to fill an intraosseous space) in a sufficiently *brief period of time* as to minimize the duration of the invasive surgical procedure (*see, e.g.*, Reiley patent at col. 1, lines 30-34), for example, to avoid subjecting the patient to an unduly long invasive process, and/or to avoid the hardening of a bone cement restorative material before it can be completely dispensed. In clear contrast, the Kriesell publication is directed to devices that are configured for prolonged implantation within a patient's body and to this end include a "porous delivery tip" that is specifically adapted for use under circumstances that involve the delivery of a "*small volume*" of medicament at an "*ultra low* controlled flow rate". The particular use for which the devices of the Kriesell reference are mechanically adapted (*i.e.*, implantation of the device in its entirety within a subject's body and prolonged, ultra low flow rate delivery of a medicament) therefore stands in clear distinction from the tool kits disclosed by the Reiley patent, which are configured for partial insertion within an intraosseous space, rapid delivery of a comparatively large volume of bone restorative material, and immediate removal of the delivery component following such rapid delivery.

The aforementioned distinctions between the systems respectively disclosed by the Reiley patent and the Kriesell publication are not merely variations in intended use, but

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<sup>1</sup> To the extent that the Kriesell publication discloses a device adapted for intracorporeal implantation for delivery of "medicinal fluids" over a long period of time, while the present claims are directed to kits that that may be used to, *inter alia*, pierce soft tissue and bone in order to gain access to an intraosseous space during a procedure that involves the delivery of restorative and/or viscous material, the Kriesell publication may be said to be nonanalogous art that should not be cited pursuant to a rejection under 35 U.S.C. § 103(a).

rather embody physical, mechanical differences that render the respective systems unsuitable for combination: the incorporation of a “porous delivery tip” that is specifically adapted for use under circumstances that involve the delivery of a “*small volume*” of medicament at an “*ultra low* controlled flow rate”, as disclosed by the Kriesell publication, into a surgical instrument (as disclosed by the Reiley patent) that requires the ability to dispense comparatively *large volumes* of bone restorative material in a sufficiently *brief period of time* as to minimize the duration of the invasive surgical procedure would render the surgical instrument of the Reiley patent unsuitable for its intended purpose. The Office has not presented any objective evidence to the contrary, and accordingly a *prima facie* case of obviousness has not been presented.

The Office argues that because the Kriesell publication discloses at paragraph [0104] of that reference that “[i]n certain instances, rate control frit may never be required”, under such circumstances, *i.e.*, when the rate control frit is not present, the device taught by the Kriesell publication could allegedly be used “to deliver a large volume of bone restorative material in a sufficient[ly] brief period of time as to minimize the duration of the invasive surgical procedure” (10/14/08 Office Action at page 4). This argument is incorrect for at least two reasons.

First, “rate control frit 95” is said by the Kriesell publication to be a “secondary rate control mechanism”, *i.e.*, in addition to the primary rate control mechanism that ensures the “low, controlled flow rate over long periods of time” as explained in the Abstract of the Kriesell publication, that is used to “fine tune the delivery rate” (*see* Kriesell publication at paragraph [0104]). In other words, in those instances where the rate control frit is not required, the primary rate control mechanism is still present to ensure that the disclosed implantable fluid delivery device provides the requisite “low, controlled flow rate over long periods of time”, and, where present, the rate control frit is used merely to “fine tune” such delivery. The Office’s contention that the absence of the rate control frit would render the device of the Kriesell publication compatible with delivery of “a large volume of bone restorative material in a sufficient[ly] brief period of time as to minimize the duration of the invasive surgical procedure” is not supported by any objective evidence in the Kriesell publication or elsewhere and such contention is therefore inapposite.

Second, the Office's contention is belied by the explicit teachings of the Kriesell publication. As shown previously, the Kriesell publication is specifically directed to a "*small-volume, very low flow rate* fluid dispensing device for precisely dispensing medicinal fluids into a patient at a *very low, controlled flow rate over long periods of time*" (Kriesell publication at Abstract; emphasis added); *see also id.* at paragraphs [0007], [0008], [0010], [0011]. The Office's suggestion that the Kriesell publication provides that removal of "rate control frit 95" would result in an embodiment that delivers "a large volume of bone restorative material in a sufficient[ly] brief period of time as to minimize the duration of the invasive surgical procedure" is not only unsupported by any objective evidence of record, but is actually contrary to the explicit teachings of the Kriesell publication. Therefore, the Office's contention in this regard cannot form the basis for a *prima facie* case of obviousness. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 U.S.P.Q. 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984) (a prior art reference must be considered in its entirety, *i.e.*, as a whole, including portions that would lead away from the claimed invention).

Finally, although the Office admits that neither the Reiley patent nor the Kriesell publication disclose a tip having about 60% to about 90% porosity (as recited in pending claim 1), the Office contends that it would have been obvious to one of ordinary skill in the art to have modified the porous delivery tip 66 of the Kriesell publication pursuant to routine experimentation in order to obtain an optimum or workable range (10/14/08 Office Action at page 3, first full paragraph). However, the Office's contention is not consistent with the actual teachings of the prior art of record, at least in the sense that the Kriesell publication teaches away from devices that are adapted to deliver medicinal fluids at other than a "small-volume, low flow rate". The Kriesell publication is said to be directed to a "small-volume, low flow rate fluid dispensing device for dispensing medicinal fluids" at "ultra low controlled flow rates over very long periods of time" (Kriesell publication at Abstract & paragraphs [0007]-[0008]), which indicates that the "porous delivery tip" could not possess characteristics that do not satisfactorily restrain the release of a fluid medicament. Based on this requirement, one skilled in the art would not be directed to modify the porous delivery tip 66 in order to provide a high degree of porosity, because high porosity would be thought to be incompatible with delivering a fluid at the requisite "ultra low" rate over the prescribed

“very long” period of time – *i.e.*, the inclusion of a tip having 60%-90% porosity could interfere with the device’s ability to satisfactorily control the release of a fluid medicament. Accordingly, the teachings of the Kriesell publication itself serve to rebut the allegation of the Office that one of ordinary skill in the art would modify the device of the Kriesell publication in order to provide a tip having about 60% to about 90% porosity, and as such, the requirements of 35 U.S.C. § 103(a) have not been satisfied. *Iron Grip Barbell Co., Inc. v. USA Sports, Inc.*, 392 F.3d 1317, 1322, 73 USPQ2d 1225, 1228 (Fed. Cir. 2004) (Applicant can rebut a presumption of obviousness based on a claimed invention that is said to fall within a prior art range by showing that the prior art taught away from the claimed invention); *In re Royka*, 490 F.2d 981 (C.C.P.A. 1974) (to establish a prima facie case of obviousness, all claim limitations must be taught or suggested by the prior art). For at least this reason as well, the rejection of claims 1-2, 9, and 56-60 under § 103(a) should be withdrawn.

Claims 3-8 stand rejected for alleged obviousness over the Reiley patent in view of the Kriesell publication and U.S. Pat. No. 6,671,561 to Moaddeb (“the Moaddeb patent”).

Applicants previously demonstrated that there is no evidence of record to suggest that those of ordinary skill in the art would have been motivated to actually combine the references’ respective teachings or to do so in a way that would have produced a claimed invention. In particular, Applicants disproved the sole rationale offered by the Office as to why it would have allegedly been obvious to one skilled in the art to modify the tip of the catheter of the Reiley patent or that of the Kriesell publication by providing a “porous layer tip” as disclosed by the Moaddeb patent (*see* 4/9/08 Reply at pages 7-8). Presently, the Office has not responded to Applicant’s argument in this regard, *i.e.*, no evidence or reasoning has been presented to suggest that it would have allegedly been obvious to one skilled in the art to modify the tip of the catheter of the Reiley patent or that of the Kriesell publication in the manner posited by the Office. Accordingly, the rejection of claims 3-8 for alleged obviousness remains improper and should be withdrawn. *Takeda Chem. Indus. Ltd. v. Alphapharm Pty., Ltd.*, 492 F.3d 1350, 1356-57 (Fed. Cir. June 28, 2007) (confirming that obviousness cannot be established based on a combination of references absent “a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements

in the way the claimed new invention does”) (citing *KSR Int’l Co. v. Teleflex Inc.*, 127 S. Ct. 1727, 1731 (2007)). *See also May 3, 2007 Memo from Margaret A. Focarino, Deputy Commissioner for Patent Operations, U.S. Patent Office* (“it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. ”) (commenting on *KSR Int’l Co.*, 127 S. Ct. 1727 (2007)).

Applicants also previously demonstrated that neither the Moaddeb patent nor any other prior art of record teaches or suggests a high-porosity tip comprising polylactic acid in accordance with claim 3 of the present application (*see* 4/9/08 Reply at pages 8-9). The Office presently cites the Moaddeb patent at column 3, line 48 for the proposition that “Moaddeb discloses that the porous tip is made of polylactic acid” (10/14/08 Office Action at page 5). However, the Office’s contention is based on an incorrect reading of the Moaddeb patent, and also relies upon on an improper interpretation of the present claims.

The Office initially alleges that the characteristics of the “porous tip” are described by the Moaddeb patent at column 4, lines 41-67 (disclosing that, *inter alia*, “[t]he porous layer is made of metal . . . should also have good thermal conductivity . . . the metal is preferably selected from [listing metals] . . .”) and column 5, lines 1-8 (providing that “[t]he porous layer increases the surface area of the tip”, which, as explained at column 5, lines 9-10, “enhances the ability of the electrode to dissipate heat during ablation”) (*see* 10/14/08 Office Action at page 3). However, the Office subsequently contends that the “porous tip” of the Moaddeb patent is “made of polylactic acid” and cites the Moaddeb patent at column 3, line 48 to allegedly support this proposition (*Id.* at page 5). It is clear from the Moaddeb patent that the allegedly “porous” material<sup>2</sup> of the tip electrode is the metal portion described at column 4, lines 41-67 and column 5, lines 1-8. The Moaddeb patent provides that the “polylactic acid” material is only present in the form of a “hydrogel layer” that coats the outer surface of the tip electrode 30 (*see* Moaddeb patent at col. 4, lines 45-50) and is not a material from which the “porous layer” described at column 4, lines 41-67 and column 5, lines 1-8 may be formed. The Office’s contention that the “porous tip” / porous layer “is made of polylactic acid” is therefore inconsistent with a proper reading of the Moaddeb patent, and cannot form the basis for a proper rejection under 35 U.S.C. § 103(a).

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<sup>2</sup> Applicants previously demonstrated that the Moaddeb patent does not teach or suggest a “high-porosity tip” as presently claimed (*see* 1/11/08 Reply at pages 5-6).

In addition, the Office's argument relies upon an improper reading of claims 1 and 3 of the present application. Claim 1 specifies that the recited kit comprises at least one catheter "having a substantially rigid high-porosity tip". Accordingly, the recited tip is "substantially rigid" and is characterized by "high porosity". Claim 3 specifies that the tip comprises polylactic acid. The instant specification provides that the tip, also referred to as the "directional diffuser 98" may be polylactic acid, or "any suitable high-porosity matter" (*see* specification as filed at page 12), thereby confirming that the polylactic acid material represents a "suitable high-porosity matter". In alleging that the Moaddeb patent discloses a porous tip that is made of polylactic acid, the Office improperly disregards the fact that the "polylactic acid" material of the Moaddeb patent is only present in the form of a "hydrogel layer" that coats the outer surface of the tip electrode 30. There is no evidence, and indeed it is not the case, that the "polylactic acid" material disclosed by the Moaddeb patent is either "high-porosity" or "substantially rigid". In alleging otherwise, the Office relies upon an incorrect reading of claims 1 and 3. Therefore, the "polylactic acid" material disclosed by the Moaddeb patent does not satisfy each and every element recited in claims 1 and 3. Accordingly, a *prima facie* case of obviousness has not been presented and the rejection of claim 3 should be withdrawn. *In re Royka*, 490 F.2d 981 (C.C.P.A. 1974) (to establish a *prima facie* case of obviousness, all claim limitations must be taught or suggested by the prior art).

Finally, the Office alleges that "[s]ince the device would be coated with the non-porous or semi-porous material, it [implies] that the coating would control the direction of flow of the composition" (10/14/08 Office Action at page 5). The Office's argument in this instance is unclear and in any event is not supported by any objective evidence. If the Office intends to allege that the "polylactic acid" material disclosed by the Moaddeb patent comprises a "non-porous or semi-porous material" in accordance with claim 4 of the present application, then the Office should provide evidence as to why one of ordinary skill in the art would be motivated to use the "polylactic acid" material of the Moaddeb patent in combination with the disclosure of the Reiley patent or the Kriesell publication. Applicants submit that such evidence does not exist. At least because the device disclosed by Moaddeb patent does not disclose delivery of any material via a catheter tip, and only describes an ablation catheter having a tip electrode (*see* Moaddeb patent at col. 3, line 6 to col. 5, line

24), one of ordinary skill in the art would not view the disclosure of the “polylactic acid” material as being relevant to systems that involve delivery of fluids from a catheter tip. Additionally, any allegation by the Office that the “polylactic acid” material disclosed by the Moaddeb patent comprises a “non-porous or semi-porous material” in accordance with claim 4 is inconsistent with the Office’s position (vis-à-vis claims 1 and 3 of the present application) that “Moaddeb discloses that the porous tip is made of polylactic acid” (10/14/08 Office Action at page 5); the “polylactic acid” material cannot be both “non-porous or semi-porous” and also “high-porosity” at the same time. In sum, the allegation of the Office regarding the alleged disclosure of a coating comprising “non-porous or semi-porous material”, in addition to being unclear, is not supported by any evidence of record, is at variance with the actual disclosure of the Moaddeb patent, and is inconsistent with the position taken by the Office with regard to claims 1 and 3 of the present application. For at least these reasons, the Office’s allegation is inapposite and cannot form the basis for a proper rejection of any pending claim under 35 U.S.C. § 103(a).

### ***Conclusion***

The Applicants submit that the foregoing represents a *bona fide* attempt to advance the present case to allowance, and that the application is now in condition therefor. Accordingly, an indication of allowability and an early Notice of Allowance are respectfully requested. If the Examiner believes that a telephone conference would expedite prosecution of this application, please telephone the undersigned at 215-568-3100.

Date: January 13, 2009

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